MDMA MEDICAL DEVICE MANUFACTURERS ASSOCIATION

May 21, 1999

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, Maryland 20852

RE: Docket No. 98N-0583
Exports: Notification and Recordkeeping Requirements

Dear Sir or Madam:

The Medical Device Manufacturers Association (MDMA) appreciates this opportunity to comment on the April 2 proposed rule published by the Food and Drug Administration to establish notification and recordkeeping requirements for persons exporting human drugs, biologics, devices, animal drugs, food, and cosmetics that may not be marketed or sold in the United States.

As the national voice for the innovators and entrepreneurs in the medical device industry, MDMA opposes this proposed rule. We believe that the proposed rule is unwarranted, does not conform with the letter or the intent of the law, and would be detrimental to the public health of populations outside the United States who rely upon American medical technology. MDMA therefore strongly urges the agency to withdraw this proposed rule.

Statutory Background

Three years ago, Congress enacted the FDA Export Reform and Enhancement Act of 1996 [Public Law 104-134, codified as amended at 21 U.S.C. §§ 381(e), 382]. This legislation significantly changed the laws governing the export of unapproved medical devices. The previous law required any manufacturer wishing to export a device not approved for use in the United States to seek prior clearance of the export from the FDA.

Congress opined that the burden of compliance with this law was a major factor in the movement of medical device research and development to other countries. Congress also recognized that the old law hampered the ability of U.S. manufacturers without overseas operations to compete with non-U.S. manufacturers in foreign markets. Recognizing that many U.S. manufacturers do business in overseas markets before their products are cleared or approved for marketing domestically, Congress made a clear move in 1996 to remove regulatory barriers to American exports of medical technology.

The FDA Export Reform and Enhancement Act provides that manufacturers may export devices that are approved in any of a select few countries -- including the countries of the European Union or the European Free Trade Association, Australia, Canada, Israel,

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Japan, New Zealand, Switzerland or South Africa -- to any country following the submission of a "simple notification" to the FDA and assuming compliance with certain other statutory requirements. For devices that are not approved in any of the listed countries, manufacturers must still obtain affirmative export clearance from the FDA.

With regard to notifying the FDA and maintaining records of exports, the statute provides that:

- an exporter of a device approved in one or more of the countries listed above and exported to that listed country shall provide a simple notification to the FDA identifying the drug or device when the exporter first begins export;

- an exporter of a device approved in one or more of the countries listed above but exported to a non-listed country shall provide a simple notification to the FDA identifying the drug or device and the country to which such drug or device is being exported; and

- any exporter of a drug or device shall maintain records of all drugs or devices exported and the countries to which they were exported.

21 U.S.C. § 382(g).

Problems with the Proposed Rule

Despite these clearly limited requirements, FDA has proposed that notifications submitted to the agency for all unapproved drugs and devices for which explicit export clearance has not been received from the FDA, regardless of whether the export is to a listed or non-listed country, must include

- the product's name;
- the type of device;
- the model number; and
- the country that is to receive the product.

64 Fed. Reg. at 15948 (proposed 21 C.F.R. § 1.101(d)). This proposal ignores the plain language of the statute, which states that notifications of exports to one of the listed countries only need to identify the device, not the destination country.

The recordkeeping proposal poses much more serious problems. The agency has proposed that for all exports of unapproved devices, the exporting manufacturer shall

keep and make available for inspection by the FDA

- records demonstrating that the product meets the specifications of the foreign purchaser;

- records demonstrating that the product is not in conflict with the laws of the importing country, which should consist of a letter (translated into English) from an appropriate official or agency within the importing country stating that the product does not conflict with the country's laws;

- copies of the labels for the exported product, which shall indicate that the product is "For Export Only"; and

- records showing that the product is not sold or offered for sale in the United States, such as documentation concerning the product and other similar products sold in the United States.

64 Fed. Reg. at 15947-48 (proposed 21 C.F.R. § 1.101(b)). For products that are not explicitly cleared for export by FDA, but which are exported instead based upon approval in one of the listed countries, the following records must be maintained in addition to those discussed above:

- the product's name;
- the type of device;
- the model number;
- the name of the consignee;
- the date of export; and
- the quantity exported.

Once again, these requirements clearly extend far beyond the simple recordkeeping requirements specified in the statute.

Why the Rule is Unwarranted

Quite simply, the statute is completely clear as to what is expected of manufacturers, and needs no regulatory interpretation or embellishment.

The proposed rule would impose additional requirements that reflect the FDA's continued belief that the agency is not simply the public-health agency for the United States, but for the entire world. Such "regulatory imperialism" is neither desired nor needed by other countries. Upon introducing the original version of the FDA Export Reform and Enhancement Act in March 1995, Senator Orrin Hatch of Utah said that his

bill "has a simple premise: that the Food and Drug Administration cannot continue to be the traffic cop for world trade in medical goods."

Even if one believes that such a role for the FDA is appropriate, the FDA does not identify in its proposed rule how the proposal would contribute to protecting or promoting the public health, either in the United States or around the world. The proposed rule adds nothing but a superfluous paperwork load upon medical device manufacturers, 93 percent of which have fewer than 100 employees and therefore would be unduly burdened by unnecessary recordkeeping.

Why the Rule Does Not Conform with the Letter or the Intent of the Law

The proposed rule would eviscerate completely congressional efforts to create a more streamlined medical-device export program through the 1996 law. As a result, many companies likely will look again to overseas locations for future product development activities, so that FDA's burdensome export policy will not hamper their efforts to introduce new products to foreign markets in a timely manner. Companies that are unable to shift activities overseas will once again be placed at a competitive disadvantage in foreign markets.

Interestingly, the FDA acknowledges in the preamble to the proposed rule that the requirements extend beyond the plain language of the statute. Yet, the FDA justifies its action by referring to duties imposed upon the Agency in cases where an exported product is later disapproved by the FDA or found to pose an imminent health hazard, as well as its general authority to implement regulations necessary for the efficient enforcement of the Federal Food, Drug, and Cosmetic Act. See 64 Fed. Reg. 15945-46. However, this justification is insufficient when the proposed regulations fly in the face of the plain language of the statute, as well as the clear intent of Congress to reduce unnecessary burdens on manufacturers.

One cannot argue that the law imposes certain substantive requirements upon exporters – such as compliance with foreign regulatory requirements – and that the FDA will be entitled to exercise its enforcement authority when it finds that a manufacturer has violated those requirements. This does not mean, however, that the agency has *carte blanche* to require exporters to maintain records to defend against such enforcement before a violation is even alleged. Furthermore, the FDA certainly may not treat such records as a substantive requirement in themselves, so that the failure to maintain them in itself justifies regulatory action.

As far as the intent of the law is concerned, one need only examine the statements of the sponsors of the legislation to determine their motivation. Again, in introducing the enacting legislation, Senator Hatch argued that "(m)anufacturers experience so much red

tape in sending their products overseas that they prefer to make them overseas," making the United States "a net loser in jobs and productivity." From these and other statements of bill sponsors, the intent of the legislation was to eliminate unnecessary regulatory and paperwork requirements from the export process.

Interestingly, in discussing the FDA's average processing times for export certificates, Senator Hatch said that "using it (average processing times) as a measure of export delays is misleading." He specifically noted that the FDA was requiring manufacturers "to go to the importing country and get a letter proving that the country has approved the device for import," and remarked that this "adds substantial time to the process upfront." [Congressional Record, March 22, 1995, S 4374-5]. Here, clearly, Senator Hatch had identified a specific, objectionable provision of the FDA's regulatory scheme as a rationale for his legislation. Incredibly, this objectionable provision has appeared in the FDA's proposed rule as an additional recordkeeping requirement beyond that mandated by law.

Why the Rule is Detrimental to the Public Health

Most medical device manufacturers conduct business worldwide, but most American exports of medical products go to other industrialized countries with sophisticated regulatory systems. The FDA Export Reform and Enhancement Act of 1996 was designed mainly to enable U.S. medical device manufacturers to sell medical technology to other countries without long-standing public-health regulations, such as Russia, China, and developing countries in Asia, South America, and Africa. To protect these countries from unsafe medical products, Congress required manufacturers seeking to export medical products to these countries to receive marketing approval in at least one other industrialized country.

This proposed rule, however, would impose a series of unnecessary notification and recordkeeping burdens upon American manufacturers, which would only serve to hinder their efforts to export world-leading medical technology to nations with no domestic medical technology manufacturing capacity of their own. Health professionals, health facilities, and government officials in these nations look to the United States for medical products that will help them enhance the quality of their citizens' lives, not to mention save lives. For companies that conduct a limited amount of sales in each of a number of these countries, the record-gathering and recordkeeping requirements that would be set forth under this proposed rule would be a major disincentive to these sales.

A prime example of the egregious nature of the proposal is the requirement that exporters secure a letter from an appropriate official of the importing country stating that the product is not in conflict with the laws of that country. MDMA believes that this requirement would create an often-insurmountable hurdle for medical device

manufacturers. Most developing countries do not have a regulatory system that is based upon premarket review and approval of devices by government officials. In such cases, the government would have no basis upon which to issue such a letter. Even in those countries with premarket review or registration requirements, the regulatory officials may not have the resources or inclination to issue such letters simply because the FDA desires them. Finally, many U.S. device manufacturers rely upon independent importers and distributors to verify compliance with foreign regulatory requirements. When choosing whether to import products from a U.S. manufacturer (for which the importer would have to contact government officials and obtain a "not in conflict" letter) and similar products, if available, from another country (for which direct interaction with government officials might not be necessary), importers would probably choose the non-U.S. products.

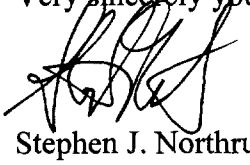
MDMA's Recommendation

Again, MDMA opposes this proposed rule entirely. To reiterate, we believe that the proposed rule is unwarranted, does not conform with the letter or the intent of the law, and would be detrimental to the public health of populations outside the United States who rely upon American medical technology.

The FDA Export Reform and Enhancement Act of 1996 set forth clearly the requirements expected of U.S. manufacturers who export products not cleared or approved by the FDA. Congress debated these requirements for over one year, from introduction of the legislation in March 1995 to passage in April 1996. After this debate, Congress set forth specific statutory language in response to burdensome regulations pointedly identified by lawmakers.

In this proposed rule, the FDA is clearly overstepping the boundaries set forth in the statutory language. MDMA recognizes that administrative interpretation of a law is sometimes required where the law is unclear, contradictory, or does not fully reflect the government's duty to protect or promote the general health and welfare of the public. This proposal, however, does not meet any of these tests, and should be withdrawn.

Very sincerely yours,



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